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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,940	01/05/2004	Thorsteinn Loftsson	016914-039	2037
21839	7590	01/25/2006		
BUCHANAN INGERSOLL PC (INCLUDING BURNS, DOANE, SWECKER & MATHIS) POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			EXAMINER CRANE, LAWRENCE E	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/750,940	Applicant(s) LOFTSSON ET AL.	
	Examiner L. E. Crane	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>05/21/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

No claims have been cancelled, no claims have been amended, the disclosure has not been amended, and no new claims have been as of the mailing date of this Office action. One Information Disclosure Statement (1 IDS) filed May 21, 2004 has been received and made of record. Examiner thanks applicant for supplying three particularly relevant non-patent literature references and notes the submission of five declarations from applicant's Loftsson and Masson.

Note to applicant: Examiner notes that the electronic scanned document database (e-dan) available here at the PTO does not include a complete scanned set of documents for the parent application (09/250,185). To insure that the instant case has a complete file history including all "NPL" documents, applicant is respectfully requested to submit copies of all cited references not already submitted for scanning to insure that the instant case has a complete electronic file history.

Claims 1-65 remain in the case.

The disclosure is objected to because of the following informalities:

Applicant is respectfully requested to update the instant disclosure in re the status of the parent application at page 1 of the disclosure.

Appropriate correction is required.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **1-6 and 34** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-5** of U. S. Patent No. **6,699,849** (PTO-892 ref. **B**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of enhancing the solubility of a benzodiazepine compound in a cyclodextrin composition, wherein enhanced benzodiazepine compound solubilities occur in the presence of a cyclodextrin at a mildly acidic pH, are directed to substantially overlapping subject matter.

Claims **7-36** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **6-21, 25-32 and 34** of U. S. Patent No. **6,699,849** (PTO-892 ref. **B**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of enhancing the solubility of a benzodiazepine compound in a cyclodextrin composition, wherein enhanced benzodiazepine compound solubilities occur in the presence of a cyclodextrin at a mildly acidic pH, are directed to substantially overlapping subject matter.

Claims **63-65** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **22-24** of U. S. Patent No. **6,699,849** (PTO-892 ref. **B**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of administration of a benzodiazepine compound containing composition, wherein enhanced benzodiazepine compound solubilities occur in the presence of a cyclodextrin at a mildly acidic pH, are directed to substantially overlapping subject matter.

Claims **45, 50, 52, 54 and 56-59** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **33 and 36** of U. S. Patent No. **6,699,849** (PTO-892 ref. **B**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of enhancing the solubility of a benzodiazepine compound in a cyclodextrin composition, wherein enhanced benzodiazepine compound solubilities occur in the presence of a cyclodextrin at a mildly acidic pH and

wherein enhanced solubility is detected, are directed to substantially overlapping subject matter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

“A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.”

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.”

Claims 1-65 are rejected under 35 U.S.C. §102(b) as being anticipated by Loftsson et al. (PTO-1449 ref. **AR**) or alternatively by references cited in Loftsson et al. numbered 12, 14, 15, 16 and 18-20 (PTO-892 refs. **R, S, T, U, V, W and X**, respectively) which applicant is assumed to have copies of as a consequence of possessing the file history for the prosecution of parent application 09/250,185.

Applicant is referred to the bottom of column 1 at page 28 and the text beginning at p. 29, column 1 through the top of column 2 of page 30 wherein the instant claimed subject matter is disclosed except for the ring-opening limitation. Applicant is respectfully requested to note the 3 to 5 fold increases in solubility of the benzodiazepine compound “medazepam” in the presence of mildly acidic conditions at page 29, column 2-column 3 and the associated disclosure that water soluble polymers also increase benzodiazepine compound solubility as illustrated in Figures 3 and 4 also found at page 29. Applicant is also requested to note that mildly basic conditions are disclosed to have a similar enhancing effect on solubility on page 29 at column 3.

Although applicant has provided evidence to support the ring opening limitation for certain active ingredients, applicant has not addressed the possibility that the ring opening is inherently part of the prior art noted in the cited Loftsson et al. reference. In the absence of convincing evidence to the contrary, examiner continues to assume that the reversible ring-opening of benzodiazepines is inherently part of the prior art disclosure and therefore that the instant cited claims are anticipated in full by the noted prior art.

Applicant's arguments filed January 5, 2004 have been fully considered but they are not deemed to be persuasive.

Examiner has re-reviewed the five declarations of applicants Loftsson and Masson, but has not found any new disclosures therein in re evidence of ring opening of benzodiazepines which would permit re-evaluation of the instant grounds of rejection.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

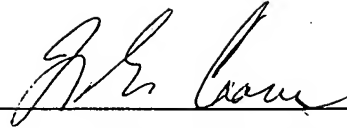
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

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LECrane:lec
01/13/2006

A handwritten signature in cursive script, appearing to read "L. E. Crane", is written over a horizontal line.

L. E. Crane, Ph.D., Esq.

Patent Examiner

Technology Center 1600